MAR 20 2000

K000439

SECTION III

510(k) Product Summary

DuraSoft® 2 Spherical, and OptiFit® Toric Soft (Hydrophilic) Contact Lenses

A. Device Summary

1. Name and Address of Applicant:

Wesley-Jessen Corporation
333 East Howard Avenue
Des Plaines, IL 60018

Contact Person:

Joseph Foos
Vice President
Scientific Affairs
Phone: (847) 294-3306
Fax: (847) 294-3853

2. Name of the Device:

Trade Name:	DuraSoft® 2 (phemfilcon A) Spherical Clear, LiteTint, Colors, and ColorBlends Soft (Hydrophilic) Contact Lenses (Lathe Cut) for Daily Wear. DuraSoft® 2 (phemfilcon A) OptiFit Toric Clear, LiteTint, Colors and ColorBlends Soft (Hydrophilic) Contact Lenses (Lathe Cut) for Daily Wear.
Classification Name:	Soft (Hydrophilic) Contact Lenses for Daily Wear.
Common Name:	D 2 Contact Lenses.
Proprietary Name:	DuraSoft® 2 (phemfilcon A) Spherical Soft (Hydrophilic) Contact Lenses. DuraSoft® 2 (phemfilcon A) OptiFit Toric Soft (Hydrophilic) Contact Lenses.

3. Identification of predicate device:

Same as above. The addition of intended use to include cosmetic correction of disfigured eyes does not change the name of the device.

4. Description of device:

The dimensions of DuraSoft® 2 (phemfilcon A) Spherical and OptiFit Toric hydrophilic contact lenses in Clear, Colors, ColorBlends and LiteTint are the same as approved in PMA N17-852.

The lens material (phemfilcon A) is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and 2-ethoxyethyl methacrylate. The physical properties of the lenses are listed below.

Physical properties of the lenses:

Specific Gravity:	1.176
Refractive Index:	1.440
Light Transmittance:	
LiteTint:	95% minimum
Color:	95% minimum
Surface Characteristics:	Hydrophilic
Water Content:	38%
Oxygen Transmissibility (Dk/L):	12.9 x $\frac{10^{-9} \text{ ml } O_2 \text{ cm}}{\text{sec ml mm Hg}}$ at 35° C

B. Statement of Intended Use

Spherical
DuraSoft® 2 Spherical (phemfilcon A) Clear, Colored, ColorBlends and LiteTint Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 0.75 diopters that does not interfere with visual acuity. The lens range in power from -20.00 to +20.00 diopters for daily wear.

OptiFit Toric
DuraSoft® 2 OptiFit Toric (phemfilcon A) Clear, Colored, ColorBlends and LiteTint Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 6.0 diopters. The lens range in power from -20.00 to +20.00 diopters for daily wear.

Prosthetic
DuraSoft® 2 Prosthetic (phemfilcon A) Soft (Hydrophilic) Contact Lenses are indicated for Daily Wear to enhance or alter the apparent eye color, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for cosmetic management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) or for occlusive therapy conditions such as diplopia, amblyopia or extreme photophobia.

The lenses are indicated for Daily Wear in not-aphakic and/or aphakic persons. The eye care practitioner may prescribe the lens for daily use with routine cleaning, rinsing and disinfection. The lens may be disinfected using a chemical (not heat) disinfection system only.

C. Technological Characteristics of the Device and Comparison

The physical properties of the device have not changed. Reference PMA N17-852 for technological device characteristics of the DuraSoft® 2 (phemfilcon A) Spherical and OptiFit Toric Soft (Hydrophilic) Contact Lenses submitted and approved by the agency.

D. Device Manufacturing Section

1. Facility:

The manufacturing of the DuraSoft® 2 Clear, LiteTint, Colors and ColorBlends Spherical and OptiFit Toric Contact Lenses is at the following facility:

Wesley Jessen - Cidra Operation
Road 173, KM 1.1
Cidra, PR 00739

Establishment Registration No.: 2648694

Reference PMA Supplement N17-852/S031 for the manufacturing of the DuraSoft® 2 Spherical and OptiFit Toric (phemfilcon A) Soft (Hydrophilic) Contact Lenses. All device-manufacturing information submitted to the FDA in the PMA Supplement N17-852/S31 & S28 is applicable to this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2000

Wesley Jessen Corporation
Mr. Joseph F. Foos
Vice President, Scientific Affairs
333 East Howard Avenue
Des Plaines, Illinois 60018-5903

Re: K000439
Trade Name: DuraSoft 2 (phemfilcon A) Colors Spherical, and OptiFit Toric Soft (Hydrophilic) Contact Lenses (Lathe Cut) for Daily Wear (Prosthetic Use)
Regulatory Class: II
Product Code: 86 LPL
Dated: February 3, 2000
Received: February 10, 2000

Dear Mr. Foos:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS STATEMENT

510(k) Number (if known) K000439

Device Name: DuraSoft® 2 (phemfilcon A) Spherical and OptiFit Toric Clear, LiteTint, Colors, Colors for Light Eyes and ColorBlends Soft (Hydrophilic) Contact Lenses (Lathe Cut) for Daily Wear

Indication for Use:

Spherical
DuraSoft® 2 Spherical (phemfilcon A) Clear, Colored, ColorBlends and LiteTint Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 0.75 diopters that does not interfere with visual acuity. The lens range in power from -20.00 to +20.00 diopters for daily wear.

OptiFit Toric
DuraSoft® 2 OptiFit Toric (phemfilcon A) Clear, Colored, ColorBlends and LiteTint Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 6.0 diopters. The lens range in power from -20.00 to +20.00 diopters for daily wear.

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DuraSoft® 2 Prosthetic (phemfilcon A) Soft (Hydrophilic) Contact Lenses are indicated for Daily Wear to enhance or alter the apparent eye color, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for cosmetic management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) or for occlusive therapy conditions such as diplopia, amblyopia or extreme photophobia.

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(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)
Conference of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter _____

Daniel W C Brown Ph.D
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K000439